REMARKS

I. STATUS OF THE CLAIMS:

Claims 1-28 are pending. Claims 19, 22-24, 26 and 27 have been amended. Applicants respectfully submit that no new matter has been added by virtue of this amendment.

II. REJECTION UNDER 35 U.S.C. § 103(a)

A. Rejection in view of EP 0 581 676

In the Office Action, the Examiner rejected claims 1-17 and 19-28 under 35 U.S.C. § 103(a) as being unpatentable over EP Patent No. 0 581 676 (hereinafter "the '676 patent"). The Examiner stated that:

> 'the amount of NSAID or ibuprofen in mg or as a ratio to the combined weight of xanthan gum and locust bean gum is met because Baichwal discloses the ratio of medicament to the heterodisperse polysaccharide is based in part upon the relative solubility of the medicament and the desired rate of release, also Baichwal discloses that "a computer aided pharmacokinetic model can be used to predict likely in-vivo drug blood levels from condition-independent in-vitro drug profiles",...[and] the dissolution as measured... is met because the claimed tablet compositions encompass the same scope it would be obvious that their dissolution properties would be the same since the same composition would have the same properties including dissolution profiles."

Independent claims 1, 10, 22, 23 and 26 recite, in pertinent part, "a t_{50} after about 12 to about 16 hours" of the NSAID (Ibuprofen).

Independent claims 19, 24 and 27 are directed to sustained release formulations "consisting essentially of" a desired amount of NSAID, e.g., 500mg to 1000mg ibuprofen, xanthan gum, locust bean gum and, as recited in claim 27, and inert diluent

In contrast, the '676 patent is directed to controlled release formulations that provide bi-modal or multiphasic release of an active agent. The bimodal or multi-phasic release "is characterized by an initial high rate followed by a slower rate as the dosage form passes the upper portion of the small intestine where absorption is maximum and finally another higher rate as the dosage form passes into the further end of the intestine where absorption is less than before" (See: '676, page 2, lines 42-44). The bi-modal or multi-phasic release properties of the formulations described therein are a result of the inclusion of a surfactant and/or wetting agent into the dosage forms (See: '676, page 3, lines 34-57). As can be seen in Figures 2-9 of the '676 patent, the formulations of Examples 3-10 (surfactant included) provide a t_{50} of about 5 to about 8 hours. Nowhere, does the '676 patent teach or suggest that the formulations described therein provide "t_{50} after about 12 to about 16 hours" as claimed in independent claims 1, 10, 22, 23 and 26 of the present invention. Furthermore, nowhere does the '676 patent teach or suggest that the formulations described therein can be formulated without a surfactant and/or wetting agent and still provide the bi-modal or multiphasic release. Applicants respectfully submit that the formulations as claimed in independent claims 19, 24 and 27 cannot include a surfactant and/or wetting agent.

In view of the arguments made above, independent claims 1, 10, 19, 22, 23, 24, 26, 27 and the claims that depend there from are not obvious over the '676 patent. Therefore, Applicant respectfully requests that the Examiner's rejection be removed.

B. Rejection over EP 0 581 676 in view of U.S. Patent No. 5,096,714

In the Office Action, the Examiner rejected claims 1-17 and 19-28 as being unpatentable over the '676 patent in view of U.S. Patent No. 5,096,714 (hereinafter "the '714 patent"). The Examiner relies on the '714 patent for its teaching of the exact amount (mg) of ibuprofen as claimed in the present invention.

In view of the arguments presented above with regard to the '676 patent, the '714 patent cannot cure the deficiencies of the '676 patent. At most, combining the teachings of the '714 patent and the '676 patent would provide one skilled in the art with a bi-modal or multi-phasic controlled release ibuprofen formulation, wherein the formulation must contain a surfactant and/or wetting agent and the t_{50} would be about 5 to about 8 hours. In contrast, the formulations claimed in independent claims 1, 22, 23 and 26 of the present invention recite "a t_{50} after about 12 to about 16 hours" and the formulations claimed in independent claims 19, 24 and 27 exclude the use of a surfactant and/or wetting agent.

In view of the arguments made above, independent claims 1, 10, 19, 22, 23, 24, 26, 27 and the claims that depend there from are not obvious over the '676 patent in view of the '714 patent. Therefore, Applicant respectfully requests that the Examiner's rejection be removed.

C. Rejection over EP 0 581 676 in view of U.S. Patent No. 5,096,714 in further view of EP 0 642 785

In the Office Action, the Examiner rejected claims 1-28 as being obvious over the '676 patent in view of the '714 patent in further view of EP 0 642 785 (hereinafter "the '785 patent"). The Examiner relied on the '785 patent for its disclosure of a hydrophobic coating wherein about 1-20% ibuprofen is coated on the tablet.

In view of the arguments presented above with regard to the '676 patent and the '714 patent, the '785 cannot cure the deficiencies of the '676 patent and the '714 patent. At most, combining the teachings of the '785 patent with the teachings of the '714 patent and the '676 patent would provide one skilled in the art with a bi-modal or multi-phasic controlled release ibuprofen formulation wherein the xanthan gum and locust bean gum may be coated with a hydrophobic coating containing about 1-20% ibuprofen, wherein the formulation must contain a surfactant and/or wetting agent and the t_{50} would be about 5 to about 8 hours. In contrast, the formulations claimed in independent claims 1, 18, 22,

23 and 26 of the present invention recite "a t_{50} after about 12 to about 16 hours" and the formulations claimed in independent claims 19, 24 and 27 exclude the use of a surfactant and/or wetting agent.

In view of the arguments made above, independent claims 1, 10, 18, 19, 22, 23, 24, 26, 27 and the claims that depend there from are not obvious over the '676 patent in view of the '714 patent in further view of the '785 patent. Therefore, Applicant respectfully requests that the Examiner's rejection be removed.

III. NONSTATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

In the Office Action, the Examiner rejected Claims 1-28 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent No. 6,093,420.

Applicants submit herewith a terminal disclaimer in view of U.S. Patent No. 6,093,420.

IV. CONCLUSION

This Amendment is being submitted together with: i) a petition for a one-month extension of time under 37 C.F.R. § 1.136(a) from January 2, 2007 to February 2, 2007; and ii) a terminal disclaimer under 37 C.F.R. 1.321(c). A check in the amount of $250.00 is enclosed herewith to cover the fees due under 37 C.F.R. § 1.17(a)(1) and 37 C.F.R. § 1.20(d). It is believed that no other fees are due. If, however, it is determined that any additional fees are due or that any fee has been overpaid, the Commissioner for Patents is hereby authorized to charge said fee or credit any overpayment to Deposit Account No. 50-0552.

Respectfully submitted,
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